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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,647	10/17/2000	Andrew S. Greenberg	TUV-005.01	3460
25181	7590	11/06/2003	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/690,647	GREENBERG, ANDREW S.	
	Examin r	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 29-56 is/are pending in the application.
- 4a) Of the above claim(s) 31-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

1. Applicant's response filed August 8, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed April 8, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.
2. Prosecution on the merits of claim 18 is reopened and is considered unpatentable for the reasons indicated below.

Response to Amendment

3. Newly submitted claims 31-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly recited methods are considered unrelated to the methods of claims 18, 29, 30, and 49-56. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, none of the methods of claims 31-48 are disclosed as working together. Furthermore, the inventions of claim 31, 32, 35, 36, 39, 40, 43, 44, 47 and 48 each recite a method of screening for inhibitors of p38 and MEK, which are different targets than

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those originally claimed and examined, i.e. ERK 1 or 2 or JNK. Because the new methods claimed seek to identify inhibitors of different compounds than those originally claimed, the inhibitors will necessarily have different structures as understood by one of ordinary skill in the art, and thus the screening process will have different modes of operation than the originally claimed screening methods, and have different outcomes because an inhibitor discovered for one target is very unlikely to inhibit another target.

Moreover, the inventions of claims 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, and 48 are drawn to methods of screening for inhibitors of lipolysis, which is broader than the originally filed claims drawn to finding an inhibitor of TNF- α induced lipolysis. Because the method of screening for inhibitors of TNF- α independent lipolysis is broader and doesn't require establishing a cause and effect relationship between TNF- α and lipolysis, the methods will have different mode of operation and different functions.

Finally, the inventions of claims 37, 38, 39, 40, 45, 46, 47, and 48 are drawn to methods of screening for inhibitors of lipolysis in fibroblasts, which are unrelated to the adipocytes of the originally claimed and examined invention. Said fibroblasts function differently in the whole organism, by making structural elements such as collagen for tissues, whereas the primary function of adipocytes is fat storage. Thus, one of skill in the art would understand that protocols for screening with fibroblasts are different than those for screening with adipocytes, and thus have different modes of operation and are likely to have different outcomes.

Accordingly, because the newly added inventions listed above are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects, and because the searches for these new inventions are divergent and not

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coextensive, and finally because a search for one does not reveal art against another, said searches present a burden on the Office to examine in one application, and their withdrawal is considered proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-48 stand withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 29, 30, and 49-56 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps which clearly identify that the claimed lipolysis is TNF- α induced. The preamble of claim 18 states that the method is drawn to screening for drugs that reduce TNF- α induced lipolysis, while step (ii) states that TNF- α is contacted with a compound that inhibits ERK1/2 and/or JNK, whereupon lipolysis activity is measured. However, no step or steps have been included for determining whether any reduction in lipolysis is TNF- α mediated. Rather, the claim as stated would screen for drugs that reduce lipolysis regardless of whether it is actually TNF- α mediated. Correction is required.

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Claims 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determining the efficacy of the screened compound in treating the range of cardiovascular diseases recited in the above-listed claims. The method is drawn to screening for compounds that reduce lipolysis, wherein the compound then claimed to be useful for treating a variety of cardiovascular diseases. However, as currently stated, the claimed screening methods contain no steps that would lead one of skill in the art to determine if such a screened compound is useful for treating any of the claimed diseases; rather, the claims are drawn only to making a determination of whether lipolysis has been reduced with no mention of treatment efficacy of the screened compound.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18 is drawn to a method of screening for drugs that reduce TNF- α induced lipolysis by isolating a compound which is an ERK1/2 inhibitor and/or a JNK inhibitor.

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In view of the specification teaching that ERK1/2 is shorthand for ERK1 and/or ERK2, and as per the “and/or” wording of the claim, the claim is drawn to the use of a compound that is optionally able to inhibit any one, two or all three of the claimed targets. However, the specification does not support claims to any compound capable of inhibiting any two or all three of ERK 1, ERK2 and JNK2. While the specification prophetically discloses inhibitors of each of the three individually, such inhibitors are not contemplated as cross reacting with any of the other two claimed targets. Furthermore, the specification does not provide any teaching, either prophetically or by way of exemplification, which would allow one of skill in the art to find such a compound that has the property of inhibiting any two or all three of the claimed targets. Finally, the examiner has been unable to locate any prior art that teaches inhibitors that act on any two or all three of the claimed targets. Accordingly, the application is not considered to contain adequate support for claims which utilize a compound that inhibit any two or all three of the claimed targets of the method.

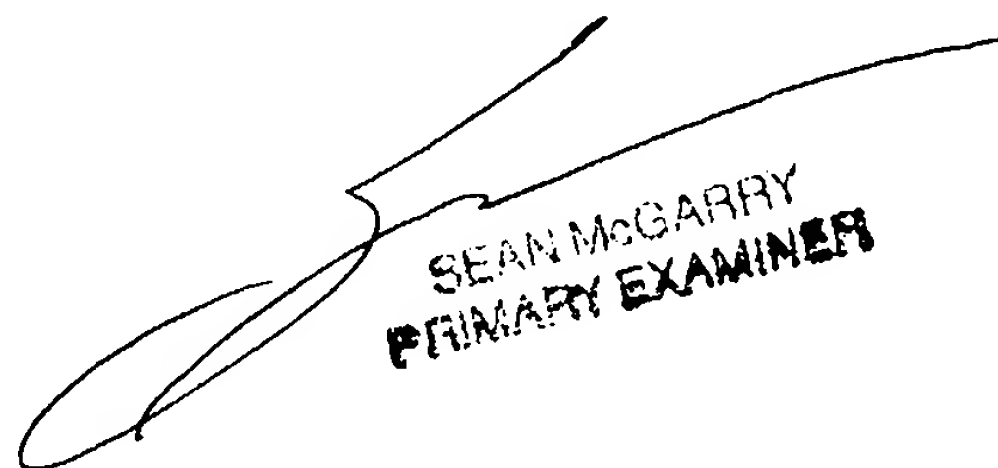
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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD



SEAN MCGARRY
PRIMARY EXAMINER